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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,530	09/18/2006	Janel Birk	18006 US PCT (HEA)	4476
51957	7590	12/19/2011		
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599				
EXAMINER				
STRANSKY, KATRINA M				
ART UNIT		PAPER NUMBER		
3734				
NOTIFICATION DATE		DELIVERY MODE		
12/19/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents_ip@allergan.com

Office Action Summary

Application No.

10/593,530

Applicant(s)

BIRK ET AL.

Examiner

KATRINA STRANSKY

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-4, 6, 7, 10-14, 19, 20 and 35-47 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 41, 46, 47 is/are allowed.
- 7) ☒ Claim(s) 1-4, 6, 7, 10-14, 19, 20, 35-40 and 42-45 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2011 has been entered.
2. Claims 1, 35, 37 and 41 are amended. Claims 1-4, 6, 7, 10-14, 19, 20 and 35-47 are pending.

Response to Arguments

3. Applicant's arguments, see Remarks, filed November 8, 2011, with respect to the rejection of claims 1 and 4 under 35 USC 102(b) in view of Wazne have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, and in light of the recent claim amendments, a new ground of rejection is made in view of Cox, US Patent No. 4,969,899.

Allowable Subject Matter

4. Claims 41, 46 and 47 are allowed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox, US Patent No. 4,969,899.
7. Regarding claim 1, Cox discloses a balloon that be used in the gastric lumen (10, Fig. 1) comprising: a shell (11, Fig. 1); a receiver formed in said shell (20, Fig. 1) having a recessed region in the shell (region inside 20, Fig. 1); a valve (36, Fig. 1) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (25, Fig. 1) being movable between a stowed position in which said retractable tubing is housed in the recessed region of the receiver (stowed position, Fig. 1) and an extended position in which said retractable tubing is withdrawn from the recessed region of the receiver and is extendable from the stomach of a patient to the mouth of the patient (tubing can be withdrawn form the recessed region of storage shell, col. 3, lines 50-60, Fig. 2) wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (col. 3, lines 50-60).
8. Regarding claims 2-3, Cox discloses that the retractable tubing is formed in one or more spirals or in a coil (tubing can be formed into spirals or coil, Fig. 1).
9. Regarding claim 4, Cox discloses that the retractable tubing is fluidly connected to the shell via an interface (tubing may make a fluid seal with reinforcement member 22, Fig. 1, col. 3, lines 40-50).

10. Regarding claim 19, Cox discloses wherein said valve is a slit valve (slit 37, col. 4, lines 10-22).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Mouri et al, US Patent No. 6,074,378.

13. Regarding claims 11-13, Cox lacks the teaching of that the retractable tubing is made of a material having a memory, a soft material comprising a radial spring, a semi-rigid material having a memory, and a shape memory alloy. However, Mouri et al. also teach that the catheter (11) may be formed from is formed of a soft material (urethane, col. 5, line 53), a semi-rigid material (shape memory alloy, Col. 5, line 55), or a shape-memory alloy to return the tubing to the proper shape (shape memory alloy, col. 5, line 55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the tubing (25) of Cox with the catheter body having an embedded coil of Mouri et al. in order to allow the tubing to recoil to a smaller profile after inflation of the balloon to prevent damage to the inner wall of the stomach (Mouri et al, col. 2, lines 29-34).

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Trick, US Patent No. 4,417,567.

15. Cox discloses the invention as claimed except wherein said valve is a septum. Trick discloses a balloon (18) having an elongated stem which is closed with a septum (24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Cox with the septum of Trick in order to allow inflation fluid to be added to or removed from the inflation tube leading to the balloon by a hollow needle (Trick, Col. 2, lines 64-68, and Col. 3, lines 1-2).

16. Claims 6-7, 14, 35-36 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Gau et al, US Patent No. 5,084,061.

17. Regarding claims 6-7 and 14, Cox discloses the claimed invention except for a receiver that is a molded valve patch bonded to the shell. However, Gau et al disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system of Gau et al to the receiver of Cox in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

18. Regarding claims 35-36 and 43-44, Cox discloses a balloon that be used in the gastric lumen (10, Fig. 1) comprising: a shell (11, Fig. 1); a receiver formed in said shell (20, Fig. 1) having a recessed region in the shell (region inside 20, Fig. 1); a valve (36, Fig. 1) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (25, Fig. 1) being movable between a stowed position in which said retractable tubing is housed in the recessed region of the receiver (stowed position, Fig. 1) and an extended position in which said retractable tubing is withdrawn from the recessed region of the receiver and is extendable from the stomach of a patient to the mouth of the patient (tubing can be withdrawn form the recessed region of storage shell, col. 3, lines 50-60, Fig. 2) wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (col. 3, lines 50-60).

19. Cox lacks the teaching of a molded valve patch bonded to the shell. However, Gau et al disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al. has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube that is bonded to the molded valve patch. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system of Gau et al to the receiver of Cox in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

20. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox and Gau et al as applied to claim 35, and further in view of Duffy, US Publication No.

2005/0171568 A1.

21. Cox and Gau et al do not expressly disclose an axle that resists withdrawal of the retractable tubing from the axle. However, Duffy teaches a torsionally loaded axle (26, Fig. 6), wherein the torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing (paragraph 0032); and the torsionally loaded axle includes a pre-grooved surface (18, Fig. 6) for accommodating said retractable tubing. In the receiver of Cox as modified by Duffy, the torsionally loaded axle can be located horizontally or vertically with respect to said receiver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the receiver of Cox as modified by Gau such that the tubing (12) is accommodated by the wheel and the axle of Duffy in order to provide a means retract the tubing (12) into the receptacle of Cox, after the balloon is inflated (Duffy, paragraph 0032).

22. Claims 37-40 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Duffy, US Publication No. 2005/0171568 A1.

23. Regarding claims 37-40, Cox discloses a balloon that be used in the gastric lumen (10, Fig. 1) comprising: a shell (11, Fig. 1); a receiver formed in said shell (20, Fig. 1) having a recessed region in the shell (region inside 20, Fig. 1); a valve (36, Fig. 1) for preventing the undesired addition or elimination of fluid from the gastric balloon;

and a retractable tubing (25, Fig. 1) being movable between a stowed position in which said retractable tubing is housed in the recessed region of the receiver (stowed position, Fig. 1) and an extended position in which said retractable tubing is withdrawn from the recessed region of the receiver and is extendable from the stomach of a patient to the mouth of the patient (tubing can be withdrawn from the recessed region of storage shell, col. 3, lines 50-60, Fig. 2) wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (col. 3, lines 50-60).

24. Cox lacks the teaching of a torsionally loaded axle structured to retract said retractable tubing into the receiver, where the receiver has a longitudinal axis and the torsionally loaded axle is substantially aligned along the longitudinal axis or substantially perpendicular with the longitudinal axis.

25. However, Duffy teaches a torsionally loaded axle (26, Fig. 6), wherein the torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing (paragraph 0032); and the torsionally loaded axle includes a pre-grooved surface (18, Fig. 6) for accommodating said retractable tubing. In the receiver of Cox as modified by Duffy, the torsionally loaded axle can be located along the longitudinal axis or substantially perpendicular to the axis of the receiver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the receiver of Cox such that the tubing (12) is accommodated by the wheel and the axle of Duffy in order to provide a means retract the tubing (12) into the receptacle of Cox, after the balloon is inflated (Duffy, paragraph 0032).

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Katrina Stransky whose telephone number is (571) 270-3843. The examiner can normally be reached on Monday through Friday, 8:30 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katrina Stransky
Examiner, Art Unit 3734

/K. S./
December 6, 2011

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734